

CLAIMS

We claim:

1. A amorphous form of 1-amino-3, 5-dimethyltricyclo-[3,3,1,1^{3,7}]decane hydrochloride (memantine hydrochloride).
2. The amorphous form of memantine hydrochloride according to claim 1, wherein an X-ray powder diffraction pattern lacks any discernible peaks.
3. The amorphous form of memantine hydrochloride according to claim 1 containing less than about 10% crystalline memantine hydrochloride.
4. The amorphous form of memantine hydrochloride according to claim 1 essentially free of crystalline memantine hydrochloride.
5. A process for preparing amorphous form of memantine hydrochloride comprising the steps of dissolving memantine hydrochloride in a solvent to form a solution, and removing the solvent from the solution to afford amorphous form of memantine hydrochloride.
6. The process of claim 5 wherein the solvent is removed by lyophilization.
7. The process of claim 6 wherein the solvent is an aqueous solvent.
8. The process of claim 7 wherein the aqueous solvent is water.
9. The process of claim 6 wherein the solvent is a C₁-C₄ alcohol.
10. The process of claim 5 wherein the solvent is removed by distillation.
11. The process of claim 10 wherein the solvent is an aqueous solvent.
12. The process of claim 10 wherein the solvent is a C₁-C₄ alcohol.
13. The process of claim 12 wherein the C₁-C₄ alcohol is methanol or ethanol.
14. The process of 10 wherein the distillation is performed at a pressure of about 400 mm Hg or less.
15. The process of claim 14 wherein the distillation is performed at a pressure of about 80 mm Hg or less.
16. The process of claim 10 wherein the distillation is performed at a pressure of from about 30 to about 80 mm Hg.
17. A pharmaceutical composition comprising an amorphous form of 1-amino-3,

5-dimethyltricyclo[3,3,1,1^{3,7}]decane hydrochloride (memantine hydrochloride) and pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, solvent, binder or stabilizer.

18. A pharmaceutical composition according to claim 17, in the form of a tablet, troche, powder, syrup, patch, liposome, injection, dispersion, suspension, solutions, capsule, cream, ointment or aerosol.

19. A method for the treating or preventing cerebral ischemia after apoplexy, open-heart surgery, cardiac standstill, subarachnoidal hemorrhage, transient cerebro-ischemic attacks, perinatal asphyxia, anoxia, hypoglycemia, apnoea and Alzheimer's disease or conditions in which N-methyl-D-aspartate (NMDA)-receptor antagonist is implicated, including a long-term non-ischemic neurodegenerative disease, comprising administrating an effective amount of an amorphous form of memantine hydrochloride according to any one of claims 1 to 4 and a pharmaceutically acceptable carrier, diluent, excipient, binder, additive, filler, lubricant, solvent or stabilizer to a patient in need thereof.